

*B7 cont*  
between about 65 and 75% by weight of said cationic quaternary amine acrylate polymer.

Please add the following claim:

*B7* *Rule 126* *3652*  
37. A polymer according to Claim 1 wherein R', R'' and R''' are independently selected from the group consisting of H, C<sub>1</sub> to C<sub>8</sub> alkyl, phenyl, tolyl and benzyl.

#### REMARKS

Favorable reconsideration and allowance of the present application is respectfully requested. Applicants and their attorney initially wish to express their gratitude to Examiner Harrison for the courtesy and assistance he extended during the recent personal interview.

Claims 1 and 3-37, including independent claims 1, 11, and 23 remain pending in the present application. In the initial Office Action, independent claim 1 was rejected over U.S. Patent No. 5,525,356 to Jevne, et al. under 35 U.S.C. §102(b), while independent claims 11 and 23 were rejected as being obvious over Jevne, et al. under 35 U.S.C. §103(a).

Jevne, et al. is directed to a polymeric, amphoteric hydrogel that has a first polymer repeating acid group and a second polymer repeating base group. (Col 2, lines 49-58). The polymeric hydrogel of Jevne, et al. can be made by combining the individual acidic and basic monomers followed by copolymerization, or by polymerizing the monomers individually and then blending the resulting polymers. (Col 3, lines 36-47). As a result of having both acid and base groups in the polymeric structure of the

amphoteric hydrogel of Jevne, et al., a zwitterion structure is said to form in which the ions of the hydrogel are substantially nonmobile. (See e.g., Col 5, lines 6-9).

On the other hand, independent claims 1, 11, and 23 require a hydrogel that is cationic and that contains an inherently antimicrobial quaternary amine acrylate polymer. For instance, as stated in the present specification, the cationic hydrogels of the present invention are able to absorb significant amounts of fluid or exudate from a wound or other skin surface abrasion. (pg. 10, lines 1-4). In addition, the cationic hydrogels can also maintain a wound in a moist condition that facilitates healing and enhances the cosmetic appearance of the wound as it heals. (pg. 10, lines 12-14). Furthermore, the inherent antimicrobial properties of the present hydrogel can also maintain or promote sterility and enhance healing when used on a wound.

As discussed in the recent interview, nowhere does Jevne, et al. disclose or suggest the use of the cationic hydrogel of the present claims. To the contrary, Jevne, et al. specifically requires the use of an amphoteric hydrogel to inhibit the migration of ions. (See e.g., Col 2, lines 23-28 and 48-58). In fact, Jevne, et al. teaches away from the use of such cationic hydrogels. For example, Jevne, et al. describes one known biopolymer that is derived from an anionic protein electrolyte component and a cationic biopolymer selected from glucosaminoglycan and collagen. (Col 2, lines 8-14). Jevne, et al. states that such known hydrogels have significant disadvantages in some applications due to the ionic structure of the adhesive. (Col 2, lines 15-22). As such, for at least the reasons set forth above, Applicants respectfully submit that independent

claims 1, 11, and 23 patentably define over Jevne, et al.

In addition to the above-mentioned rejection, independent claim 1 was also rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,152,307 to Shibahara, et al. Shibahara, et al. is directed to a water-in-oil polymer emulsion that is used in waste-water treatments and papermaking operations. The water-in-oil polymer emulsion is formed from 30 to 70% by weight of an aqueous solution of an ethylenically unsaturated monomer and 70 to 30% by weight of a hydrophobic organic liquid in the presence of a surfactant. (Col 2, lines 7-41). Examples of suitable hydrophobic organic liquids are said to be hydrophobic aliphatic hydrocarbons and aromatic hydrocarbons, animal and vegetable oils, as well as denatured oils thereof. (Col 2, lines 67-68 and Col 3, lines 11).

In contrast, independent claim 1 is directed to an aqueous hydrogel. The aqueous hydrogel can, in one embodiment, comprise between about 15 to 95% by weight of a cationic quaternary ammonium acrylate polymer. (See e.g., pg. 7, lines 3-6). For example, to form the aqueous hydrogel, the quaternary ammonium polymer can be prepared in an aqueous medium and form the hydrogel *in situ*, or the polymer can be prepared in an aqueous medium, dried and converted into a powder that can be reconstituted in an aqueous media as a hydrogel. (pg. 8, lines 7-10). Such an aqueous hydrogel can improve exudate absorption, moisture retention, and the like.

As discussed in the recent personal interview, Shibahara, et al. completely fails to disclose the use of an aqueous hydrogel as defined in independent claim 1. For

example, as stated above, Shibahara, et al. requires the use of a hydrophobic organic liquid as part of the water-in-oil emulsion. In fact, Shibahara, et al. actually teaches away from an emulsion that does not contain such a hydrophobic organic liquid by stating the following:

When the amount of the hydrophobic organic liquid, or the total amount of the hydrophobic organic liquid and a hydrophobic vinyl monomer when the latter is present in the hydrophobic organic liquid, is less than about 30% by weight, the stability of the produced emulsion will deteriorate over the course of time. (Col 5, lines 15-20).

Such an amount of a hydrophobic organic liquid, if used in conjunction with the hydrogel of independent claim 1, could lessen the ability of the hydrogel to retain moisture and absorb wound exudates. Thus, at least because independent claim 1 requires an aqueous hydrogel that does not contain such an amount of a hydrophobic component, Applicants respectfully submit that independent claim 1 patentably defines over Shibahara, et al.

In addition, the above-cited references were also cited to reject dependent claims 3-10, 12-22, and 24-36. Applicants respectfully submit, however, that at least for the reasons indicated above relating to corresponding independent claims 1, 11, and 23, claims 3-10, 12-22, and 24-36 patentably define over the references cited. Nevertheless, Applicants also note that the patentability of dependent claims 3-10, 12-22, and 24-36 certainly does not hinge on the patentability of independent claims 1, 11, and 23. In particular, these claims possess features that are independently patentable, regardless of the patentability of claims 1, 11, and 23.

Besides the above-mentioned rejections, claims 1-36 were rejected under 35

U.S.C. §112 as being indefinite. Thus, in accordance with the Examiner's suggestions, Applicants have amended the applicable claims to better clarify certain aspects of the present invention. Further, claims 1, 2 and 4-10 were also rejected under the judicially-created doctrine of obviousness-type double patenting over U.S. Patent No. 5,800,685. In response, Applicants are submitting herewith a Terminal Disclaimer signed by the current owner of the present application and the '685 patent.

In the Office Action, the Examiner also indicated that the first sentence of the specification should be changed to reflect any claim to priority being made. Thus, as suggested, Applicants have amended the specification as set forth above. Further, it was also noted that the "citation of prior art" in the preliminary amendment should be cited in a PTO-1449 form. However, as indicated by the Examiner in the recent interview, Applicants are not required to resubmit such form because the references were already submitted in a PTO-1449 on February 14, 2000.

Thus, for at least the reasons set forth above, Applicants respectfully submit that the present claims patentably define over all of the prior art of record and meets all of the requirements of 35 U.S.C. §112. It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Harrison is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this response.

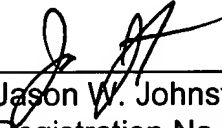
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Respectfully submitted,

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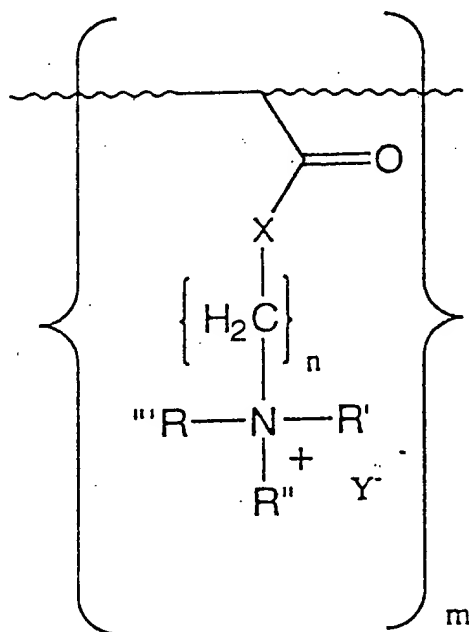
## APPENDIX A

### IN THE SPECIFICATION:

This application is a divisional of application Serial No. 09/144,727 filed September 1, 1998, now issued as U.S. Patent No. 6,039,940, which is a continuation-in-part of [pending] application Serial No. 08/738,651 filed October 28, 1996, which is now [and] issued as U.S. Patent No. 5,800,685.

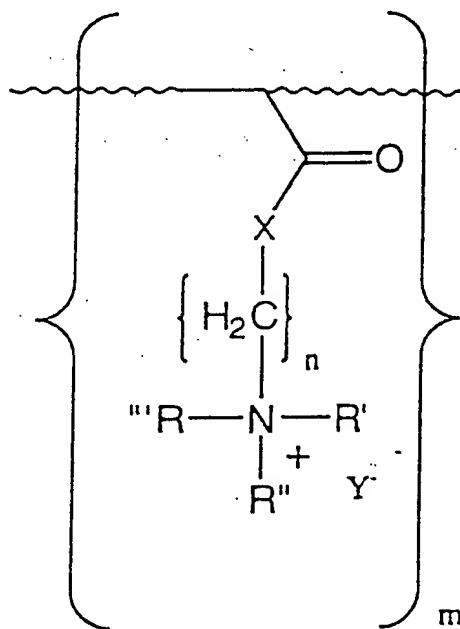
### IN THE CLAIMS:

1. (Amended) A cationic aqueous hydrogel comprising an [An] inherently antimicrobial cationic quaternary amine acrylate polymer [of] having the formula:



wherein  $n$  is an integer of 2 to 3;  $R'$ ,  $R''$  and  $R'''$  are independently selected from the group consisting of H,  $C_1$  to  $C_{16}$  alkyl, aryl, arylamine, alkylamine, alkaryl and aralkyl;  $X$  is selected from the group consisting of O and NH;  $Y^-$  is an acceptable anionic counterion to the  $N^+$  of the quaternary amine and  $m$  is an integer greater than 50,000.

11. (Amended) A wound dressing comprising a cationic hydrogel containing from about 15 to 95 weight percent by weight of an inherently antimicrobial cationic quaternary amine acrylate polymer [of] having the formula:



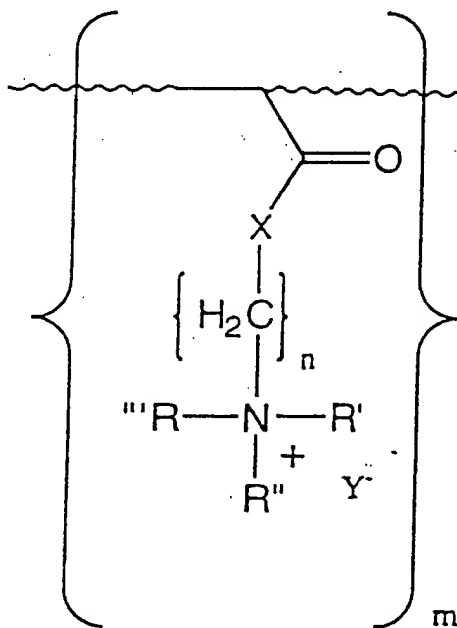
wherein n is an integer of 2 to 3; R', R'' and R''' are independently selected from the group consisting of H, C<sub>1</sub> to C<sub>16</sub> alkyl, aryl, arylamine, alkylamine, alkaryl and aralkyl; X is selected from the group consisting of O and NH; Y<sup>-</sup> is an acceptable anionic counterion to the N<sup>+</sup> of the quaternary amine and m is an integer greater than 50,000.

21. (Amended) A wound dressing according to Claim 11 wherein the hydrogel contains between about 61 and 90% by weight of said cationic quaternary amine [polyacrylate] acrylate polymer.



22. (Amended) A wound dressing according to Claim 21 wherein the hydrogel contains between about 65 and 75% by weight of said cationic quaternary amine [polyacrylate] acrylate polymer.

23. (Amended) A device for the dressing of wounds comprising a substrate having fixedly attached thereto a wound dressing comprising a cationic hydrogel containing from about 15 to 95 weight percent by weight of an inherently antimicrobial cationic quaternary amine acrylate polymer having the formula:



wherein n is an integer of 2 to 3; R', R'' and R''' are independently selected from the group consisting of H, C<sub>1</sub> to C<sub>16</sub> alkyl, aryl, arylamine, alkylamine, alkaryl and aralkyl; X is selected from the group consisting of O and NH; Y<sup>-</sup> is an acceptable anionic counterion to the N<sup>+</sup> of the quaternary amine and m is an integer greater than 50,000.

35. (Amended) A device according to Claim 23 wherein the hydrogel contains between about 61 and 90% by weight of said cationic quaternary amine [polyacrylate] acrylate polymer.

36. (Amended) A device according to Claim 35 wherein the hydrogel contains between about 65 and 75% by weight of said cationic quaternary amine [polyacrylate] acrylate polymer.